

KO 8319/



APR 10 2009

Edwards

510(k) Summary

Submitter: Edwards Lifesciences LLC
Contact Person: Martin A. Kaufman
Director - Regulatory Affairs
martin_kaufman@edwards.com
(ph) 949.250.2708
(fax) 949.250.3630

Date Prepared: October 27, 2008

Trade Name: Edwards™ dETlogix™ annuloplasty ring

Classification Name: Class II, CFR 870.3800 Annuloplasty Ring, KRH

Predicate Device(s): GeoForm® annuloplasty ring (K032250)
Carpentier-Edwards Physio® annuloplasty ring (K926138)
Carpentier-Edwards Classic® annuloplasty ring (K831949)

Device Description: The dETlogix™ annuloplasty ring, model 5100, is constructed of titanium alloy and has a sewing ring margin that consists of a layer of silicone rubber, covered with polyester velour cloth sewn with a single seam.

Indications for Use: The dETlogix annuloplasty ring, model 5100 is intended for the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement.

Comparative Analysis: It has been demonstrated that the dETlogix annuloplasty ring is comparable to the predicate devices in design, intended use, materials, and principal of operation.

Functional/Safety Testing: The dETlogix annuloplasty ring has successfully completed design verification testing.

Conclusion: The dETlogix annuloplasty ring is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 10 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Edwards Lifesciences, LLC.
Martin A. Kaufman
Director of Regulatory Affairs
One Edwards Way
Irvine CA 92614

Re: K083191

Trade/Device Name: dETlogix annuloplasty ring, model 5100
Regulation Number: 21 CFR 870.3800
Regulatory Class: Class II
Product Code: KRH
Dated: February 26, 2009
Received: March 2, 2009

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083191

Device Name: dETlogix annuloplasty ring, Model 5100

Indications for Use:

The dETlogix annuloplasty ring, model 5100, is indicated for the correction of mitral valvular insufficiency where the lesions are not severe enough as to require total valve replacement.

The decision to undertake valvuloplasty can be made only after visual analysis of the lesion present. The most favorable conditions for valvuloplasty using an annuloplasty ring are a combination of a distended natural valve ring associated with supple valve cusps and normal chordae tendineae.

The remodeling valvuloplasty technique with a prosthetic ring may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral annulus.

For Type I mitral insufficiencies with no subvalvular lesions and normal valvular movements, this ring technique used alone is sufficient. However, the ring technique must be associated with mitral valvuloplasty repair in Type II insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae tendineae, or chordal hypertrophy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083191

Page 1 of 1